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EXAMINER	
KHARE, DEVESH	
ART UNIT	**PAPER NUMBER**
1623	

DATE MAILED: 08/11/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/614,298	SICHTNIK, LASZLO	
	Examiner	Art Unit	
	Devesh Khare	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-29* is/are pending in the application.

4a) Of the above claim(s) *1-13* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *14-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *7/8/2003*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Applicant's election with traverse claims 14-29 of Group I is acknowledged. The traversal is on the ground(s) that " a search and examination of the entire application can be conducted without a serious burden on the Office". This is not found persuasive because the applicants' claims 1-10 (Group II, class 514) are drawn to a method of treating otitis media and otitis externa with the composition of Group I (class 514 and 536).). In the instant case the process for using the product can be practiced with another materially different product i.e. a method of treating otitus media and otitis externa in a subject can be practiced with another materially different product such as diclofenac potassium (see abstract, U.S. Patent 6,107,343). Claims 11-13 (Group III) are drawn to an apparatus for administering a pharmaceutical powder composition (class 422), which would be burdensome to the examiner, as it cannot be assumed that the burden of search under three different classes are the same.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the

right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-13 are withdrawn from further consideration by the examiner, 37

CFR 1.142(b), as being drawn to a non-elected invention.

Claims 14-29 are before the examiner and an action on the merits of said claims is contained herein below.

Minor objections

Claims 18,21,26 and 29 are objected to because of the following informalities:

In claims 18,21,26 and 29 the chemical registry number for [4-chlorphenyl]-3,4-

dichlor-benzol-sulfonamidum could not be found.

Appropriate correction is required.

35 U.S.C. 112, second paragraph rejection

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims **14-29** are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(A) In claims 14 and 22, in the absence of the chemical formula or name of the active ingredients "a local anaesthetic agent, an antimicrobial agent, an anti-inflammatory agent, and an integrator" claimed, render the claims indefinite wherein applicant fails to articulate by chemical name or structural formula, requisite to identifying the active ingredients of matter claimed.

(B) Claims 22-29 do not confer patentable distinction on the previously claimed composition claims 14-21 therefore claims 22-29 are being a substantial duplicate of claims 14-21. Claims 22-29 fail to further limit invention of claims 14-21. The preamble of the composition claims 22-29 provides intended use therefore does not limit the claim.

Claims which depend from an indefinite claim which fail to obviate the indefiniteness of the claim from which they depend are also seen to be indefinite and are also rejected for the reasons set forth supra.

35 U.S.C. 103(a) rejection

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 14-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Petrus (U.S.Patent 6,093,417) in combinations with Sallmann et al. (Sallmann) (U.S. Patent 6,107,343) in view of Pollard et al. (Pollard) (WO 92/11016).

Claims 14-25 are drawn to a pharmaceutical composition comprising pharmaceutically effective amounts of a local anaesthetic agent, an antimicrobial

agent, an anti-inflammatory agent, and an integrator. Additional claim limitations include further comprising an anti-caking agent lactose powder; anaesthetic is norcain powder; antimicrobial agent is [4-chlorphenyl]-3,4-dichlor-benzol-sulfonamidum powder; anti-inflammatory agent is boric acid powder; integrator is urea powder; and claims 21&29 consists essentially of norcain powder, [4-chlorphenyl]-3,4-dichlor-benzol-sulfonamidum powder, boric acid powder, urea powder, and lactose powder.

Petrus teaches a composition to treat ear disorders comprising penetration enhancers, anaesthetics and/or analgesics, anti-inflammatory agents and anti-infective agents (abstract). Petrus discloses the use of anaesthetics to relieve the pain associated with ear disorders (col.4, lines 34-38). Two major classes of local anaesthetics are disclosed, the ester class includes benzocaine and the amide class includes lidocaine (col. 4, lines 43-55). Petrus also discloses anti-microbial or anti-infective agents such as sulfonamides (col. 8, lines 53-55). The anti-inflammatory agents are disclosed in cols. 7 and 8, however the boric acid powder is not disclosed. Petrus differs from the applicant's invention in that Petrus does not provide the claimed anti-inflammatory agent (boric acid), integrator (urea) and the anti-caking agent (lactose powder).

Sallmann teaches an ophthalmic and aural composition for treating otitis (abstract). Sallmann discloses the use of tonicity enhancing agents such as boric acid and urea (col. 5, lines 17-22). Sallmann does not disclose the use of the anti-caking agent lactose.

The Pollard reference is drawn to a pharmaceutical composition for the treatment of cystic fibrosis (abstract). Pollard discloses the use of lactose powder as a pharmaceutically acceptable carrier in non-pressurized powder compositions (page 2, lines 30-32).

Therefore, one of ordinary skill in the art would have found the composition comprising a local anaesthetic agent, an antimicrobial agent, an anti-inflammatory agent, an integrator and an anti-caking agent for treating otitis media and otitis externa, to have been obvious at the time the invention was made having the above cited references before him. Since Petrus discloses a composition to treat ear disorders comprising penetration enhancers, anaesthetics and/or analgesics, anti-inflammatory agents and anti-infective agents; Sallmann discloses the use of an anti-inflammatory agent such as boric acid and an integrator such as urea in an aural composition and Pollard discloses the use of anti-caking agent lactose powder as a pharmaceutically acceptable carrier in non-pressurized powder compositions, one skilled in the art would have a reasonable expectation for success in combining the teachings of these references to accomplish a composition containing pharmaceutically effective amounts of a local anaesthetic agent, an antimicrobial agent, an anti-inflammatory agent, an anti-caking agent and an integrator for the treatment of otitis media and otitis externa. The motivation for doing so is provided by Petrus, which discloses a topical composition comprising an active agent to provide pain

relief and an antimicrobial agent to combat infection when administered into the external ear canal (col.3, lines 5-24).

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Devesh Khare whose telephone number is 571-272-0653. The examiner can normally be reached on Monday to Friday from 8:00 to 4:30.
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson, Supervisory Patent Examiner, Art Unit 1623 can be reached at 571-272-0661. The official fax phone numbers for the organization where this application or proceeding is assigned is (703) 308-4556 or 308-4242. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

JAMES O. WILSON
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

Devesh Khare, Ph.D.,J.D.
Art Unit 1623
August 3,2004